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Review

Death during or following surgical procedure and the allegation of medical negligence: An overview

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Abstract

A great variety of mishaps can occur during or following the administration of anesthesia and operative or investigational procedures that do not necessarily convey an error of judgment or negligence on the part of the surgeon or the anesthetist. However, all deaths occurring during the course of anesthesia and surgery or within a reasonable period thereafter (commonly referred to as peri-operative period) have to be reported to the police as these deaths cannot be regarded as natural. Despite the death occurring due to some pre-existing disease or some co-existent condition, there may be a tendency on the part of the relatives of the deceased to impute negligence on the part of the anesthetist and/or the surgeon merely because of the fact that the death was closely associated with the anesthesia and surgical intervention. As such, any death suspected to be caused, or contributed to, by any of these procedures needs to be adequately investigated both from the point of view of the relatives of the deceased as well as instituting future safety measures. This paper examines the medical, ethical and legal aspects of such deaths with reference to the allegations of medical negligence in these cases.
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1. Introduction

Informative and sociologic awareness of the public about their perceived rights and prerogatives is evident from the spate of malpractice actions against the health care workers. No wonder, therefore, that deaths occurring during or within a short period after surgical, invasive diagnostic procedure, or administration of anesthetic may become the subject of a medicolegal investigation. There have been many attempts to quantify the incidence of death during and following the administration of anesthesia. Beecher and Todd[1] collecting data during 1948 to 1952 at the 10 US hospitals reported the death rate associated with anesthesia as a primary or contributory factor to be 1 in 1560 cases. The Baltimore Anesthesia Study[2] investigated all deaths occurring within 24 h of anesthesia during 1953 to 1959 to determine the role of anesthesia in each death and calculated the mortality rate associated with anesthesia as 4 in 10,000 cases. The study reported anesthesia as the primary cause of death in 1.3 and a contributing factor in 2.7 per 10,000 cases.

Memery[3] investigated in-hospital deaths over a period of 10 years (1955–1964) to ascertain the role of anesthesia in post-operative mortality and reported the incidence as 1 in 3145 cases. Keenan and Boyan[4] reported the incidence of deaths due to anesthesia-induced cardiac arrest as 0.9 per 10,000 while another study[5] reported anesthesia-induced cardiac arrest mortality rate of 0.3 per 10,000. A 30-year study of deaths in a Cape Town hospital[6] reported the anesthetic mortality rate as 0.19 per 10,000 as compared to an overall operative mortality rate of 8.99 per 10,000. Another study from Australia[7] reported that the incidence of death (within 24 h) related to anesthesia declined from 1 in 5500 in 1960 to 1 in 26,000 in 1984.

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Some other studies have also reported a decline in the incidence of anesthesia related deaths.[8]

Anesthesiologists and surgeons in NHS hospitals in the UK voluntarily reported deaths within 30 days of surgery during 1985 and 1986 to assess the contribution of various factors to each death and concluded that anesthesia played some role in 14.1% of all the reported deaths.[9] According to a report,[10] Simpson reviewed 500 deaths during anesthesia and reported that 56% of these deaths were due to the disease for which the operation was conducted, 30% were the outcome of shock and inevitable risks of operation itself, 8% were caused by the risks and complications of anesthesia while 6% could be pinned upon overdosage, wrong administration or bad choice of the anesthetic. Based on these findings, deaths attributable to anesthesia and/or surgery may be due to anesthetic agent, improper technique/inexperience, and functional problems.

2. Deaths attributable to anesthetic drugs

Direct action of the anesthetic agent may sometimes result in cardiac arrhythmias and cardiac arrest. Risks of respiratory inadequacy following the use of drugs to produce myo-neural blockage has been reported. There is evidence that halothane can cause liver necrosis and malignant hyperpyrexia, associated with tachycardia, hyperpnoea, cyanosis, and stiffening of muscles that may lead to death.[11] Many studies have reported the hazards of anesthetic agents administered by injection and/or inhalation as well as the drug interactions.[12–15]

3. Respiratory embarrassment

Respiratory embarrassment may occur during and/or after the anesthesia or a surgical procedure. Intra-operative problems are likely to effect oxygenation even in an otherwise normal lung resulting into a compromised oxygen supply to the tissues. Some of the iatrogenic precipitating factors for hypoventilation may include use of barbiturates, tranquilizers, etc. as pre-medication. Hypoventilation may occur in deep planes of anesthesia with intercostals paralysis and diaphragmatic impairment. Packs and retractors may press upon the diaphragm and impede movement of the lungs. Patients with neuromuscular weakness and chronic obstructive airway disease are particularly prone to hypoventilation.[16] Elderly patients with fixed thoracic cage, depressed ciliary activity and suppressed cough reflex are also prone to risk.[17]

Regurgitation may take place in a paralyzed patient who cannot vomit; hence, contamination of tracheobronchial tree may take place with secretions, gastric contents, food, blood, etc. that may be aspirated into the respiratory tract. Aspiration of pus may lead to multiple abscesses of lungs. Aspirate gastric contents may cause chemical irritation that may ultimately lead to pulmonary edema and chemical pneumonitis. Tracheal intubation, instituted to prevent dissemination of vomitus, pus, or regurgitated matter, may prove inadequate because material may leak past the inflated cuff.[18] However, finding of gastric contents in the airways on autopsy, needs careful scrutinization to trace some evidence of its clinical/ante-mortem origin because such contents can be present in some part of the air passage due to agonal or even post-mortem spillage.

Rupture of an emphysematous bleb during operative procedures from inhalation anesthesia may lead to pneumothorax. It is also one of the complications of subclavian vein catheterization or supra-clavicular brachial plexus block. If accumulation of air in the pleural cavity continues and intra-pleural pressure rises, tension pneumothorax may develop that may cause mediastinal shift effecting the heart and great vessels. Occasionally, misplacement of the tracheal tube may lead to atelectasis.[19]

Transfusion of massive or relatively excessive amounts of fluids, plasma expanders or blood may lead to pulmonary edema. The effect of airway negative pressure, which increases the gradient between capillary pressure and alveolar pressure, producing transudation may be another possibility.[20]

4. Cardiac embarrassment

Normal cardiac function depends upon a balanced action of the two mutually antagonistic divisions of the autonomic nervous system, viz. the sympathetic that stimulates and parasympathetic that depresses the heart. Fear, severe pain, extremes of temperature and decrease in the tension of carotid sinus, may cause stimulation of the sympathetic system, which increases myocardial irritability and leads to premature ventricular beats and fibrillation. Conversely, the stimulation of peripheral fibres, respiratory tract, pleura, peritoneum, abdominal viscera, or pulling on their attachments and increase in the tension of carotid sinus, may lead to parasympathetic stimulation resulting into sudden slowing of the heart, hypotension and even cardiac asystole.[21]

Hypoxia acts as a contributory factor in producing cardiac embarrassment[22] in two ways: firstly, hypoxia, acidosis and hypotension from pain, fear and other causes sensitize the myocardium to the action of catecholamines eventually leading to ventricular fibrillation and secondly, some anesthetic agents, or diseases such as coronary sclerosis also sensitize the myocardium to catecholamines and reflex nervous stimulation.[23] Stimulation of the vagi in the presence of hypoxia may lead to sudden asystole. Vagal stimulation per se is unlikely to occur spontaneously when the circulation is hypoxic, but respiratory irritation causing bronchial spasm may result in both vagal over-activity and hypoxia.[24] Patients suffering from a natural over-activity of the parasympathetic system are more likely to have such a reflex cardiac arrest.

Other contributing factors towards cardiac embarrassment may be traced to the anesthetic agent. Almost all inhalation anesthetics cause peripheral vasodilatation and cardiac depression leading to hypotension and ischaemia

of the cardiac muscle. Oxygen starvation to the brain and heart may occur due to hypotensive episodes during the operation and the effect of such episodes may be cumulative. The heart, after beating under hypoxic conditions for some period, progressively builds up a greater and greater debt and finally gives way.[22] Furthermore, heart and brain that are already burdened with drugs (pre-medication, anesthetic agents) are more likely to succumb to insignificant deprivation.

5. Other complications

Hepatic complications associated with general anesthesia involving various anesthetic agents have been known almost from the time of discovery of anesthesia.[25] However factors other than anesthetic may be involved in causing hepatic dysfunction, namely preexisting liver disease, hypoxia, hypotension, blood transfusion, infection and drug therapy.

Renal complications in the form of decrease in renal blood flow, glomerular filtration and excretion of water plus electrolytes have been reported. Factors contributing towards such response may include hemodynamic alterations, changes in blood pressure and cardiac output and renal splanchnic vasoconstriction.[26]

6. Deaths attributable to technique/equipment

Equipment failure is a relatively rare cause of anesthetic deaths these days. However, the following types of human errors have been reported[27–29]: (1) Technical – in which the action taken is not the action intended, may arise from deficiencies of technical skill or from poor design of equipment. (2) Judgmental – in which the action represents a bad decision, arising from lapses in the training or poorly developed decision-making skills and (3) Monitoring and vigilance failure – in which there lies an essential failure to recognize or act upon an observation/finding requiring a response. Circumstances under which a human error may occur include the following: (1) An endotracheal tube may get dislodged, kinked or obstructed by mucous, blood or growth, (2) The separated cuff may block the larynx, (3) Maneuvering of the head and neck associated with laryngoscopy may cause glotic edema, injury to teeth and cervical vertebrae, (4) Veins may get injured in procedures of the neck resulting in air embolism and (5) The malfunction of anesthetic machines may lead to hypoxia, anoxia, and anesthetic overdose or underdose.

7. Deaths attributable to factors other than anesthesia

These may include: (1) Those directly caused by disease or injury for which the operation or anesthesia was required. Here the injury in itself may be such as to result in death, with anesthesia or surgery playing no role, but usually undertaken in the remote hope that the victim's life may be saved. (2) Those caused by a disease or abnormality other than that for which the procedure was being undertaken, as for example, surgical mishaps (like inadvertent tearing or cutting of a major blood vessel) and/or post-operative events (like phlebothrombosis, pulmonary embolism, etc.), which may follow but are neither related to the anesthetic procedure nor to surgery. (3) Unforeseeable problems, as for example, victims of hemoglobinopathies, especially sickle cell anemia are unduly susceptible to low oxygen tension in blood and may pose a hazard to the unaware surgeon or anesthetist.[30] Coronary thrombosis may supervene in a patient operated upon for injuries. Inflammable mixtures of anesthetic gases with air or oxygen may get ignited through sparks from electric appliances or diathermy apparatus and may cause explosions and fire. Electrical appliances like defective cauteries, defibrillators and diathermy equipment are potentially dangerous and have been reported to cause death.[31] Halothane and/or succinylcholine may produce malignant hyperthermia in patients with inherited muscular defects.[32]

8. Ethical considerations

Until the 1950s, physicians routinely obtained 'assent', the general agreement of the patient to have a procedure. Mid-century, society-wide rights reorientation brought about a new interpretation of individual liberties and autonomy.[33] The 1957 legal case of Salgo v Trustees of Leland Stanford Hospital codified the modern concept of 'informed consent'. The judge clarified the difference between informed consent and assent by declaring that, "A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form (the) basis of an intelligent consent by the patient to a proposed treatment…."[34] The idea of informed consent – the corner stone of the patient physician relationship, is rooted in the ethical principle of respect for patients' autonomy, which asserts that patients have a right to self-determination. The goal of informed consent is to maximize the ability of the patient to make substantially autonomous informed decisions. The modifier 'substantial' was proposed because it is unreasonable to expect a patient to be fully informed.[35,36] The present day informed consent has seven components:

(1) Decision-making capacity – defined as the ability to make a particular decision at a specific time includes the ability to understand medical problems, proposed treatments, alternatives, options to refuse treatment, foreseeable consequences of accepting or refusing proposed treatments, and express a preference based on rational and reasoning. The surgeon and anesthetist must permit the patient to make decisions when there are no questions about the decision-making capacity, but they need to actively evaluate the decision-making capacity for patients whose decision-making capacity

has been temporarily altered, who do not have legal decision-making authority, or who have preexisting limitations in decision-making capacity.[37]

(2) Voluntariness – meaning that a procedure should be performed only on a competent patient who participates willingly. Competent patients have the legal and moral right to refuse treatment even in life-threatening emergency situations. It is often hard for physicians to accept that a patient wishes to make what the physician perceives to be a foolish decision. The case of Shine v Vega[38] exhibits the complexity of these situations. Vega, the emergency department attending physician, intubated the trachea of a competent adult Shine who had reported for the treatment of an asthma attack, despite the refusal. On appeal, the Massachusetts Supreme Court stated that the competent patient has a right to refuse potentially life-sustaining treatment, even if her decision is considered unwise.[39]

(3) Disclosure aiming to provide information relevant to the decision-maker and the decision to be made helps patient make good decisions, builds trust and is a fundamental component of the obligation to respect a patient's autonomy, however, the opinions differ as regards the extent of disclosure[40–42]. Courts also consider how the information was given and as such, the informed consent discussion should occur in a setting conducive to decision-making, giving the patient a chance to ask questions and consider answers. Preprinted consent forms may not be relied on to reliably impart information, although video may be an effective way of communicating information.[43–45]

(4) Recommendations of preferable options and the advantages and disadvantages of each option, thus allowing the patient to receive the benefit of the expertise and to understand the reasons for the recommendations. However, it must be left to the patient to decide, which choice best fit his/her priority.

(5) Understanding the risks and benefits of the proposed procedures, the recommendations made, and why those recommendations were made is necessary for the patient, however, it is difficult to determine whether a patient fully understands the informed consent discussion, and many patients may not.[46] Patients often misunderstand terms that are common to physicians such as nasogastric tube, fasting and antibiotics.[47] On the other hand, a patient's subjective assessment of the adequacy of the informed consent process has sociologic, ethical, and legal importance, but it is not an assessment of the patient's ability to comprehend the data.[48] Most research relating to understanding is based on surrogate end points of recall of information or patient satisfaction. However, 'recall' is an inexact science and does not fully test understanding. Good recall of information may not accurately reflect the patient's understanding and ability to use the information to make decisions and poor recall is not equivalent to poor understanding.[49]

(6) Decision is to be taken by the patient after considering the information and/or the recommendations of the surgeon and the anesthetist. However, studies reveal that the patients vary in their preferences for participation in decision-making. In a study assessing the acceptance of invasive medical device, 10% of patients wanted patient-based decision-making, whereas 21% wanted physician-based decision-making.[50] Data from a 4-year study of patients with chronic diseases such as hypertension, diabetes, heart disease and depression found that 27% wanted active participation in decision-making while 69% of the patients wanted to leave decision-making to physicians.[51] When a patient refuses anesthesiologist's recommendations or requests a technique the anesthesiologist feels inappropriate, the focus of conversation moves from informed consent to 'informed refusal', the requirements for which are similar to informed consent in that the patient should be substantially well versed about the risks, benefits and alternatives before declining.[52]

(7) Autonomous authorization means how anesthesiologists and surgeons acknowledge the responsibility to respect a patient's right to self-determination and to follow a self-chosen plan by obtaining informed consent. This authorization being the expression of the patient's self-determination and the basis of informed consent.

9. Medicolegal considerations

In case of a death occurring during the course of anesthesia and surgery, there is a usual tendency on the part of the relatives and/or their counsel to raise a finger of accusation towards the doctor because of death being so closely related to the intervention. Hence, the public and private interest would be best served by displaying independence and reporting the issue to the police so that the death believed to be caused, or contributed to, by any of these procedures may be adequately investigated.

The doctor–patient relationship is an interpersonal relationship called 'empathy', i.e. ability to share one another's feelings and interests. Failure of empathy and communication often act as precipitating factors for negligence suits. Hence, informed consent of the patient or the relative/guardian with particular regard to physical status of the patient, and associated disabilities must be obtained and properly documented.[53]

Documentation of pre-anesthetic evaluation and assessment of the patient, and pre-operative record of the events, are of vital importance and can prove to be a tool for retrospective analysis of the information.[54]

It is important to establish the identity including the type of surgery to be performed and the part of body to be operated upon. The doctor should ensure and make the patient feel his (doctor's) presence during and after the operation, the so-called identification and re-identification.

Clear and adequate instructions must be issued to the nursing staff of the recovery room and any specific problem to look for and to guard against must be clearly indicated. Patient should be kept under personal supervision at least until all monitoring, mechanical ventilation, drainage of secretions and the like are attended to.

10. Autopsy – limitations and precautions

It is well known that oxygen starvation to brain and heart may occur due to hypotensive episodes during the operation that may have a cumulative effect and one slip in the technique can trigger a chain-reaction ultimately leading to death. Whereas surgical mistakes being anatomical may be appreciable during the autopsy but the anesthetic mistakes being physiological may no longer be appreciable after death except where overdose with specific drug is involved. Accordingly, the findings of the autopsy surgeon alone may not be sufficient to explain death and therefore, it is advisable to hold a discussion across the autopsy table involving forensic expert/autopsy surgeon, anesthetist and the surgeon/clinician concerned.

Surgical interventions and its sequelae, especially in abdominal and thoracic procedures may pose certain problems at autopsy. Introduction of some surgical and anesthetic devices like airways, indwelling catheters, intravenous cannulae, wound drains, chest tubes, etc. during and subsequent to surgery are likely to interfere with the findings. Their proper placement and patency should be assessed. A full range of specimens for histological toxicological, bacteriological examinations and those required to exclude hazards associated with blood or fluid transfusions, must be collected.

Specimens for histological purposes should be preserved particularly to exclude any cardiovascular disorder including occult conditions like myocarditis as well as for assessing the severity of disease for which the operation was carried out. Histological examination of the brain is imperative to demonstrate the effects of hypoxia, particularly in the region of Sommer's area of the hippocampal gyrus and cerebellum, where changes are expected even if the victim suffers hypoxia for a short period.

For the purpose of toxicological examination, it may be necessary to obtain samples by the biopsy techniques prior to autopsy so as to avoid loss of gases due to exposure of tissue to the air. Alveolar air should be collected with a syringe by pulmonary puncture before opening the chest. Blood should be collected under liquid paraffin. Alternatively, glass tubes with aluminium foil or Teflon-lined caps need to be used to avoid the escape of volatile substances. A lung by clamping the main bronchus may be removed and retained in a nylon bag to analyze the head-space gas. Some fat from the mesentery, some skeletal muscular tissue, and a portion of the brain should be retained in addition to routine viscera.

Adequate blood, urine and other body fluids may have to be collected for bacteriological and other related issues. Extraneous specimens like residual solutions, medication containers, samples of gases used as anesthetics may have to be collected in occasional cases.

11. Role of expert in the court

The legal process of judging the standard of care by non-clinician members of the court may be a troublesome experience for the anesthetist or surgeon. However, in the present scenario, the courts often invest expert evidence with a trust and confidence, and as such, the overriding duty of the expert is to the court through expressing an independent opinion, rather than representing the interests of a professional colleague. Accordingly, the deaths associated with surgical intervention or invasive diagnostic procedures may necessitate following considerations:

(1) Where the disease or injury was in an advanced stage and a heroic effort was made in the hope of saving the life of the patient, there must have been some foreseeable chance of success or even mitigation of symptoms.
(2) Where the death is attributed solely or partly to a disease or disability other than for which the intervention had been carried out, there must have been a careful pre-operative evaluation considering risk : benefit ratio and appropriate modification of the operative and/or anesthetic procedures taking an account of the known adverse conditions. Issues of negligence may creep up when some occult disease process remains undetected and the test for liability would be that whether a doctor of reasonable skill and competence could have diagnosed the same under similar conditions.
(3) Where death is attributed to some unusually difficult surgical procedure as may happen inadvertently from a true accident, from some anatomical abnormality or failure of equipment, examination and advice by the concerned expert assumes utmost importance. Injury to some large blood vessel, leaving of some pack/swab/instrument in the body may directly be covered under the concept of 'error' or 'incompetence'.
(4) Appropriating relative contribution between the anesthetist and the surgeon is extremely difficult. Each one is responsible for negligent acts of oneself and not of the other, as there exists no master–servant relationship between the two. However, under exceptional circumstances, one may become liable for the wrongful acts of the other, which one observes or should have observed and permits to pass unheeded without inviting the attention of the other.

12. Some court judgments

''Negligence, as a tort, is the breach of a duty caused by omission to do something which a reasonable person would do, or doing something which a prudent and reason-

able person would not do. It has many manifestations – it may be active or passive negligence, collateral negligence, comparative negligence, concurrent negligence and willful or reckless negligence.''[55]

''An error in diagnosis or treatment is not negligence, provided proper care and skill had been exercised by the medical practitioner, to the best of his ability and in good faith. A mistaken diagnosis is not a negligent diagnosis. It has been firmly established that a medical practitioner should not be held negligent simply because one of the risks inherent in an operation of that kind occurs or because he has failed to warm the patient of every risk involved in a proposed course of treatment''[56]

The Courts have elucidated the gravity of charge to be made in a case of negligence as: ''A charge of professional negligence against a medical man is serious. It stands on a different footing than a charge of negligence of motorcar driver. The consequences are far more serious as it affects the doctor's professional status and reputation hence the burden of proof is correspondingly greater. A doctor is not to be held negligent simply because something went wrong or there was a misadventure or an error of judgment. He is liable only when the standard of care was below the standard of care of a reasonably competent practitioner in his field, so much so that his conduct becomes inexcusable''[57]

In yet another case the court ruled that, ''When death of the patient occurred within the four walls of the operation theatre where the patient's relatives had no access whatsoever, the onus lies on the doctors in the Operation Theater, to explain the events that had happened there. It is the duty of the doctors to prove or rule out the cause of death for which they are allegedly held responsible.''[58]

In one case, the Court observed ''there is an increasing tendency on part of the litigants to indulge in speculative and vexatious litigation and adventurism which the Fora seem to readily oblige. We think such a tendency needs to be curbed.''[59]

However, in another case the Delhi High Court decreed that, ''to express grievance strongly against a professional does not amount to defamation by any stretch of imagination. Difference of opinion on the basis of which the plaintiff alleged negligence on part of the defendants does not amount to defamation. Filing a case or raising a bonafide controversy regarding the treatment given does not constitute defamation.''[60]

13. Conclusion

In view of such judgments, it won't be wrong to say that along with the corporatisation of healthcare, grew another subsidiary i.e. medical negligence, which has almost taken the shape of a business with patient, patients' guardians/relatives as well as legal professionals and legal firms just waiting for a chance to make some money out of the misery of another person. The only prevention against such allegations is to be careful about various aspects associated with surgery and anesthesia as for example, reasonable skill and care at each and every step by every person involved in the health care delivery, understanding the significance of Informed Consent, and also the rights of the patient and appreciating the importance of adequate and complete documentation of all the processes involved in providing health care to the patient.

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